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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,970	08/18/2005	Tatsuro Irimura	62870(70232)	1465

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BOSTON, MA 02205

EXAMINER

LIU, SUE XU

ART UNIT	PAPER NUMBER
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1639

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/524,970	Applicant(s) IRIMURA ET AL.	
	Examiner Sue Liu	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 6-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/18/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

1. Claims 1-16 are currently pending.
Claims 1-5 are being examined in this application.

Election/Restrictions

2. Applicant's election without traverse of Group I (Claims 1-5) in the reply filed on 1/16/07 is acknowledged.
3. Claims 6-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1-16/07.
4. Applicant's election without traverse of the following species:
A.) MAH lectin;
B.) Erythorocytes;
C.) mesenchymal stem cell;
in the reply filed on 1/16/07 is acknowledged.

Priority

5. This application is filed under 35 U.S.C 371 of PCT/JP03/10461 (filed on 08/19/2003), which claims priority to JAPAN 2002-239979 (8/20/02).

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6. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers (JAPAN 2002-239979) have been placed of record in the file.

Information Disclosure Statement

7. The information disclosure statement filed 8/18/2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the following references are missing date information as listed in the filed IDS: CB and CD. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

Sequence Rule Compliance

8. "In order to expedite the processing of applications, minor errors pertaining to compliance with the sequence rules may be handled with the first Office action." See MPEP 2427.01.

9. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2).

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However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 for the reason(s) below:

The instant disclosure recites lists of sequences in the specification (e.g. see p. 21, 36, etc.), which sequences are not identified by their corresponding SEQ ID Nos. The instant disclosure also recites lists of sequences in the drawings, which sequences are not identified by their corresponding SEQ ID Nos in the “BRIEF DESCRIPTION OF THE FIGURES AND TABLES” of the instant specification.

Applicants are requested to amend the instant specification and/or claims accordingly.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

11. Claims 4 and 5 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4 and 5 are not been further treated on the merits.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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13. Claim 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "... sugar chains serving as an indicator", which is unclear. It is not clear which entity (or entities) is the "indicator(s)".

Claim 2 recites the term "O-binding sugar chains", which is indefinite. Neither the instant specification nor the claims specifically define this uncommon term, which is not recognized in the art to have a specifically defined structure and/or meaning.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Note: the instant claim numbers are in bold font.)

15. Claims 1-3 are rejected under **35 U.S.C. 102(b)** as being anticipated by Yim et al (PNAS. Vol. 98 (5): 2222-2225; 2/27/2001; cited in IDS).

The instant claims recite a lectin library for *discriminating glycoproteins or cells, diagnosing serum or cells or fractionating glycoproteins or cells*, which comprises at least one

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kind of lectin selected from plural kinds of lectins, on the basis of affinity for cells, pseudo-cells, glycoproteins or sugar chains serving as an indicator.

The recitation in “*italic*” of the instant claim (Claim 1) is construed as intended use for the claimed “lectin library”. The portion of the claim (Claim 1) that is underlined is construed as product by process limitation.

Yim et al, throughout the publication, teach lectin libraries generated from Maachia amurensis hemagglutinin (MAH) lectin (Abstract), which reads on the elected species of MAH. The reference teaches various MAH mutants (a lectin library) that recognize various carbohydrate chains on erythrocyte (reads on the elected species of “erythrocyte”) (p. 2222, top of right col.; p. 2224, right-left col.; Figure 3), which reads on the lectin library of **clms 1 and 3**. The reference’s teaching also reads on the process of making the lectin library (selection based on affinity for erythrocytes) of **clms 1 and 3**.

The instant specification does not specifically define the term “O-binding sugar”, which may be interpreted to mean “O-glycosylation” or “O-linked carbohydrate chains” (see spec. p. 13, para 2). The reference teaches MAH binds to sialic acid residues (sugar chain) on erythrocytes, which the sialic acid residues are linked to the erythrocytes through O-glycosylation, as evidenced by the instant specification (Figure 4, p. 4, para 2; especially p. 11, para 3; p. 14, para 2). Furthermore, MAH lectin is known in the art to “preferentially binds to O-linked carbohydrate chains containing sialic acid” (Imberty et al., Journal of Biological Chemistry. Vol. 275(23): 17541-17548, 2000; cited in IDS). Thus, it is an inherent property of the MAH lectin to bind “O-linked” carbohydrate chains. Therefore, the MAH wild-type and mutants (a library of lectins) that were selected by binding to erythrocytes (containing the O-

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linked carbohydrate chains) read on the lectin that “recognize” “O-binding sugar chains” of **clm**

2.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 15 of copending Application No. 10/468543 (US 20040091938; filed 12/29/03). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the ‘543 application reads on the claims of the instant claims.

The ‘543 application claims:

Claim 13: “A lectin library for determining differences in sugar chains, comprising a plurality of different lectin molecules, wherein: (a) each lectin molecule has a sugar chain-binding region comprising at least 11 amino acid residues and including one or

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more conserved amino acids therein; (b) the lectin library comprises at least one recombinant lectin molecule that is derived from Maackia amurensis hemagglutinin (MAH) and which has a sugar chain-binding region with at least one amino acid substitution, insertion, or deletion; and (c) the lectin library comprises at least one lectin molecule that is capable of binding a sugar chain.

Claim 15: The lectin library of claim 13, wherein the different lectin molecules are selected from a collection of lectin molecules by contacting the collection of lectin molecules with one or more sugar chains.”

These claims read on the “lectin library” and lectin that binds to “O-binding sugar chain” as recited in the instant claim, because MAH preferentially binds to O-linked carbohydrate (sugar) chains (as evidenced by Imberty et al).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

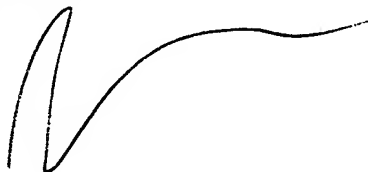
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON EPPERSON
PRIMARY EXAMINER

A handwritten signature in black ink, consisting of a stylized 'J' followed by a long, sweeping horizontal line.

SL
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3/19/07